

## REMARKS

Upon entry of the foregoing amendments, claims 1, 7, 10, 13-22, 25-47 and 49-62 are under consideration. Claims 1, 7, 20, 22, 30, 51, and 54-57 are amended, and claims 2-6, 8-9, 11-12, 23-24, 47, 48 and 62 are cancelled. Support for the amendment to claim 1 can be found at least at page 59, Table 2B, and in the claims as originally filed. Claims 7, 21, 51, and 54-57 have been amended made to correct grammatical and typographical errors and antecedent basis. No new matter has been added.

### I. Claims Objections

Claims 51 is objected to because it is missing the period punctuation mark. Applicants have amended claim 51 to include a period at the end of the claim. Claims 54 and 56 are objected to because the recitation “claims” should be singular. Applicants have amended claims 51, 54 and 56 accordingly. As such, the objections with respect to claims 51, 54 and 56 have been overcome and should be withdrawn.

Claims 22 and 47 are objected to as being of improper dependent form for failing to further limit the subject matter of the previous claim. Claim 47 has been cancelled. This objection is therefore moot with respect to claims 47. Claim 21 has been amended recite “a non-translatable mRNA molecule *specific for* a gene encoding a protein of interest”. Claim 22 further limits the non-translatable mRNA molecule of claim 21 to an antisense nucleic acid, hairpin RNA or microRNA, each of which silence gene expression *in a sequence specific manner*. As such, Applicants submit claim 22 properly limits amended claim 21 and request that this rejection be withdrawn.

### II. Claim Rejections-35 U.S.C. § 112, second paragraph

Claims 1, 7, 10, 13-20, 31-40, 46, 47, 49, 50 and 54-62 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. According to the Examiner, the recitations “constitutive tissue specific”, “tissue specific” and “wherein said nucleic acid molecule regulates constitutive tissue specific transcription of an operably linked nucleotide sequence of interest” each render claim 1 and the claims which depend therefrom indefinite. The Examiner also contends that claims 54 and 56 lack antecedent basis for the limitation “The transgenic plant”,

and that claims 55 and 57 likewise lack antecedent basis for the limitation “The seed”.

Applicants traverse with respect to the claims as amended herein.

Claim 1 has been amended to delete the “constitutive tissue specific” recitation. Claim 1 has further been amended to clarify that the nucleic acid molecule regulates transcription of a nucleotide sequence of interest *when* operably linked to said nucleic acid molecule (i.e., the nucleotide sequence of interest is not part of the product encompassed by claim 1). As such, Applicants submit amended claim 1 is definite and request that this rejection be withdrawn.

Claims 54, 55, 56 and 57 have been amended to replace the word “The” with the word “A”, as suggested by the Examiner. As amended, claims 54 and 56 recite “A transgenic plant” and claims 55 and 57 recite “A seed”. As such, Applicants submit claims 54-57 are definite. This rejection has therefore been overcome with respect to claims 1 and 54-57 and should be withdrawn.

### **III. Claim Rejections-35 U.S.C. § 112, first paragraph**

Claims 1, 7, 10, 13-20, 31-40, 46, 47, 49, 50, 54, 55 and 58-62 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the specification does not provide descriptive support for an isolated nucleic acid molecule that is “less than 487 base pairs in length comprising the nucleotide sequence of SEQ ID NO: 5”. Applicants have amended claim 1 to delete the recitation of an isolated nucleic acid molecule that is “less than 487 base pairs in length comprising the nucleotide sequence of SEQ ID NO: 5”. As such, Applicants submit this rejection has been overcome and should be withdrawn.

Claims 1, 7, 10, 13-20, 30-40, 46, 47, 49, 50, 54, 55 and 58-62 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. According to the Examiner, it is not clear what is meant by “constitutive tissue specific” given the definition for “constitutive” in the specification, and the data which shows that SEQ ID NO: 5 is active in plant tissues that are above and below ground. The Examiner further contends that the specification does not mention any isolated nucleic acid molecule less than 487 base pairs in length comprising SEQ ID NO: 5. Lastly, the Examiner contends that claims 20 and 30, with respect to a nucleotide sequence encoding a CaaX prenyl protease, is not enabled because the

specification nor the prior art teach an isolated nucleotide sequence encoding a CaaX at the time the application was filed.

As previously indicated, Applicants have amended claim 1 to delete the phrases “constitutive tissue specific” and “less than 487 base pairs in length comprising the nucleotide sequence of SEQ ID NO: 5” from the claim. Applicants have also deleted “CaaX prenyl protease” from claims 20 and 30. As such, Applicants submit this rejection has been overcome and should be withdrawn.

#### **IV. Claim Rejections-35 U.S.C. § 103**

Claims 1, 7, 10, 13-22, 25-47 and 49-61 remain rejected under 35 U.S.C. § 103(a) as being obvious over WO 2002/16655 (Harper 1), in light of Genbank Database Accession No. AX510060, WO 2002/16655, SEQ ID NO:2071 (Harper 2), and Genbank Database Accession No. AX507376, WO 2002/16655, SEQ ID NO:4755 (Harper 3), each published on February 28, 2002, and hereinafter collectively referred to as “Harper”. According to the Examiner, the truncated constitutive promoter claimed in the instant application would inherently have the same functional characteristics as the promoter disclosed in Harper. Applicants traverse with respect to the claims as amended herein.

Amended claim 1 recites an isolated nucleic acid molecule consisting of SEQ ID NO: 5, wherein the nucleic acid molecule regulates transcription of a nucleotide sequence of interest when operably linked to said nucleic acid molecule.

Applicants traverse the rejection of independent claim 1 and its dependent claims on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness. A *prima facie* case of obviousness requires that “either the reference(s) must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the reference(s).” *See* MPEP 706.02(j) citing *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Knowledge of the disclosure provided by the instant application must be put aside when determining whether the claimed invention would have been obvious. *See* MPEP 2142.

To support the conclusion that the claimed invention is directed to obvious subject matter, the Examiner has cited and combined up to three references. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one ordinary skill in the art. *See MPEP §2143.01*, citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007). Furthermore, a statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine or modify the teachings of the references. *See MPEP §2143.01*, citing *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (emphasis original).

There is no objective reason provided by the Harper references, either alone or in combination, that would lead the skilled artisan to combine and/or modify these references, nor is there any evidence that any resultant modification to these references to yield a promoter capable of regulating nucleic acid transcription would have been predictable. These references fail to provide the skilled artisan with a reasonable expectation that truncating the hydroxypyruvate reductase (HPR) promoter disclosed in Harper by almost 200 base pairs would successfully yield a promoter with retained nucleic acid transcription activity. Moreover, the Harper references do not teach the specific isolated nucleic acid molecule consisting of SEQ ID NO: 5, wherein the sequence has promoter activity, in that it will regulate transcription of an operably linked nucleotide sequence, as specified in the claims as amended herein.

Harper discloses an 1161 base pair nucleic acid sequence (SEQ ID NO:2071) which encodes HPR, and a 487 base pair nucleic acid sequence (SEQ ID NO:4755) which encodes an HPR promoter sequence, each of which comprises the sequence of Applicants’ SEQ ID NO:5. Additionally, Harper discloses that SEQ ID NO:4755 will function as a promoter in response to an abiotic stress (*see* Harper et al. page 4, lines 3-5)-- an inducible promoter. With respect to SEQ ID NO: 4755, there is nothing in Harper that discloses anything less than SEQ ID NO: 4755 in its entirety as having promoter activity. Likewise, there is nothing in Harper which suggests that anything less than SEQ ID NO: 4755 in its entirety would be desirable. As such, the Harper

references fail to provide the skilled artisan with any objective reason to truncate SEQ ID NO 4755, or any other promoter disclosed therein.

The Examiner contends that promoter deletion analysis is routine in the prior art to determine regions necessary for minimal activity and therefore it would have been obvious to conduct promoter deletion analysis on the HPR promoter of SEQ ID NO: 4755 of Harper to arrive at the claimed invention (*see Office Action, pages 10-11*). Even if the Examiner's assertion that making truncations frequently results in the creation of a constitutive core promoter sequence was true, with which Applicants do not agree, Harper fails to provide the skilled artisan with any guidance whatsoever regarding which location along 487 base pair sequence of SEQ ID NO: 4755 should be truncated to arrive at a promoter sequence capable of transcription, such as the 288 base pair nucleotide sequence of SEQ ID NO:5, as claimed herein. Thus, based on the teachings of Harper, the skilled artisan would not be able to predict which of the thousands of possible truncated variants of Harper's SEQ ID NO: 4755 would retain nucleic acid transcription activity with any reasonable expectation of success, let alone the specific promoter according to SEQ ID NO:5 of the instant invention.

As such, there is no objective reason provided in the Harper references, alone or in combination, that would lead the skilled artisan to arrive at the claimed invention. Moreover, there is no evidence that the results generated by combining and/or modifying these references would have been predictable at the time the instant invention was made. Any suggestion that it would have been obvious to truncate the promoters of Harper to arrive at the promoter of SEQ ID NO:5, as required by amended claim 1, is an improper application of hindsight based on Applicants' disclosure in the instant application. Thus, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness and request that this rejection be withdrawn.

## CONCLUSION

Applicants believe that the claims, as amended, are in condition for allowance. If the Examiner has any questions, the Examiner is invited to contact the undersigned by telephone.

Respectfully submitted,

/Lillian Horwitz/

Ivor R. Elrifi, Reg. No. 39,529  
Cynthia Kozakiewicz, Reg. No. 42,764  
Lillian Horwitz, Reg. No. 57,040  
Attorneys for Applicant  
c/o MINTZ, LEVIN  
Tel: (617) 542 6000  
Fax: (617) 542 2241  
**Customer No. 30623**